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Bezeichnung:

Fibrillator für Herzchirurgie

⑦①

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**DE 28 11 325 A 1**

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plementären Transistoren ( $T_2, T_4$ ) geschaltet sind, deren Kollektorelektroden miteinander und über einen Kondensator ( $C_1$ ) mit den Basiselektroden der ersten beiden symmetrisch angeordneten Transistoren ( $T_1, T_3$ ) verbunden sind, daß die Emittierelektroden des zweiten Transistorpaares ( $T_2, T_4$ ) an entgegengesetzten Polen einer Serienschaltung aus zwei Batterien ( $U_1, U_2$ ) anliegen, wobei der Mittelabgriff (0) der beiden Batterien ( $U_1, U_2$ ) über einen Widerstand ( $R_1$ ) auf die beiden Emittierelektroden des ersten Transistorpaares ( $T_1, T_3$ ) geführt ist, und daß eine Elektrode ( $E_1$ ) mit den beiden Kollektorelektroden des zweiten Transistorpaares ( $T_2, T_4$ ) verbunden ist, während die andere Elektrode ( $E_2$ ) am Mittelabgriff (0) anliegt.

2. Fibrillator für Herzchirurgie nach Anspruch 1, dadurch gekennzeichnet, daß bei einem der Transistoren des zweiten Transistorpaares ( $T_2, T_4$ ) zwischen Basis- und Emittierelektrode ein Widerstand ( $R_2$ ) eingefügt ist.
3. Fibrillator für Herzchirurgie nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß in die Emittierelektroden des ersten Transistorpaares ( $T_1, T_3$ ) Leuchtdioden ( $D_1, D_2$ ) eingefügt sind.
4. Fibrillator für Herzchirurgie nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß der Generator im Tonfrequenzbereich schwingt.

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GESELLSCHAFT  
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MÜNCHEN

Ottobrunn, 8.03.1978  
8295  
BT01 Bd/gö

### Fibrillator für Herzchirurgie

Die Erfindung betrifft einen Fibrillator für Herzchirurgie, bestehend aus einem Generator und zwei Elektroden, die während einer Herzoperation kurzzeitig an der Oberfläche des Herzens angelegt werden.

Es ist bekannt, daß bei einer Belastung des menschlichen Körpers mit niederfrequenten Strömen entsprechender Stärke oder mit Gleichstromimpulsen, die Herz- und anderen Muskelfasern in eine fortgesetzte ungeordnete Tätigkeit versetzt werden (Fibrillation). Sie besteht aus rhythmischen, aber nicht synchronen Dehnungen und Kontraktionen einzelner Fasern, so daß die Funktion des Gesamtsystems gestört ist, z.B. Herzkammerflimmern.

Bei Operationen am offenen Herzen wird diese Tatsache dazu benutzt, durch elektrische Reize eine ventrikuläre Fibrillation hervorzurufen. Zu diesem Zweck bringt man Elektroden mit ungefähr  $1 \text{ cm}^2$  Oberfläche an zwei Stellen der Herzoberfläche an und legt eine 50Hz Spannung an die Elektroden. Der elektrische Strom stimuliert und depolarisiert gleichzeitig einen großen Teil des Herzmuskels. Zur gleichen Zeit depolarisieren die Impulse, die auf dem normalen Weg das Herz erreichen, die endocardiale Oberfläche. Durch das Ineinandergreifen der beiden Prozesse ergibt sich eine unregelmäßige Depolarisation, die verschiedene Zonen des Myocards in unterschiedliche Erregungszustände versetzt und für die Fibrillation verantwortlich ist. Um diesen Zustand zu erreichen, sind hohe Stromdichten erforderlich, da ein genügend großer Bereich depolarisiert werden muß. Bis zu 10 Volt sind erforderlich, um die Fibrillation zu

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troden des ersten Paares aus zwei symmetrisch angeordneten komplementären Transistoren jeweils miteinander verbunden sind und die Kollektorelektroden auf die Basiselektroden des zweiten Paares aus zwei symmetrisch angeordneten komplementären Transistoren geschaltet sind, deren Kollektorelektroden miteinander und über einen Kondensator mit den Basiselektroden der ersten beiden symmetrisch angeordneten Transistoren verbunden sind, daß die Emittierelektroden des zweiten Transistorpaares an entgegengesetzten Polen einer Serienschaltung aus zwei Batterien anliegen, wobei der Mittelabgriff der beiden Batterien über einen Widerstand auf die beiden Emittierelektroden des ersten Transistorpaares geführt ist, und daß eine Elektrode mit den beiden Kollektorelektroden des zweiten Transistorpaares verbunden ist, während die andere Elektrode am Mittelabgriff anliegt.

Die weitere vorteilhafte Ausgestaltung des Fibrillators ist aus den Unteransprüchen ersichtlich.

Die besonderen Vorteile des erfindungsgemäßen Fibrillators bestehen darin, daß er als kleines, stiftförmiges, netzunabhängiges Gerät in der Form eines Operationsbesteckes mit fest eingebauten Elektroden genau wie dieses behandelt werden kann, d.h. voll sterilisiert am Operationstisch griffbereit liegt. Die handliche Ausführungsform ermöglicht ein rasches Überstreichen des Herzmuskels, wobei eine Stimulation an mehreren Stellen des Herzmuskels erfolgt und dadurch mit Sicherheit die Fibrillation erreicht wird. Der erfindungsgemäße Fibrillator ist auch sehr sparsam im Stromverbrauch, da er sich erst beim Anlegen der Elektroden an der Herzoberfläche selbsttätig einschaltet. Ferner ist er kurzschlußsicher.

Ein Ausführungsbeispiel der Erfindung ist in der Zeichnung dar-

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Fig. 2 zeigt einen kompletten Fibrillator gemäß der Erfindung in der äußeren Form eines L-förmigen Operationsbesteckes. Der kurze Schenkel 5 enthält die Elektroden  $E_1$  und  $E_2$ . In einem Hohlzylinder 4 aus Isolierstoff ist der Generator untergebracht. Der lange Schenkel 6, der vorzugsweise aus Metall mit plangeschliffener Oberfläche hergestellt ist, enthält die Batterien  $U_1, U_2$ .

In Fig. 3 ist eine Schallquelle  $S$  dargestellt, die an die Elektroden  $E_1, E_2$  des Fibrillators anschaltbar ist. Die Kontaktierung der Schallquelle  $S$  erfolgt über einen ringförmigen Kontakt 9, an dem die Elektrode  $E_2$  des Fibrillators anliegt, sowie über eine Kontaktplatte 8, die isoliert in den ringförmigen Kontakt 9 eingelegt ist und mit der Elektrode  $E_1$  in Verbindung gebracht wird.

Die elektrische Schaltung des Fibrillators nach Fig. 1 funktioniert folgendermaßen: Sobald das Herz mit den Elektroden  $E_1, E_2$  in Berührung kommt, entlädt sich der Kondensator  $C_1$  über den Herzwiderstand, der durch den Widerstand  $R_H$  dargestellt ist, unter der Annahme, daß der Kondensator  $C_1$  gegenüber dem Bezugspotential am Mittelabgriff 0 im Zeitpunkt der Betrachtung negativ aufgeladen ist. Durch das auftretende  $\frac{du}{dt}$  fließt ein Strom in die Basis-elektrode des Transistors  $T_1$ , wodurch der Transistor  $T_2$  leitend wird. Der Kondensator  $C_1$  wird dadurch positiv aufgeladen (Mittkopplungseffekt). Ist die Aufladung beendet, geht  $\frac{du}{dt}$  gegen 0, der Transistor  $T_1$  sperrt und damit auch der Transistor  $T_2$ . Der Kondensator  $C_1$  entlädt sich wieder über den Herzwiderstand  $R_H$  mit umgekehrter Stromrichtung, so daß die Transistoren  $T_3$  und  $T_4$  leitend werden bis der Kondensator  $C_1$  negativ aufgeladen ist. Anschließend wiederholt sich der eben beschriebene Entladungsvorgang, so daß eine symmetrische Rechteckspannung mit einer durch die Größe des Kondensators  $C_1$  gegebenen Frequenz auftritt.

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(54) **Fibrillation induction method for implantable devices.**

(57) A method and apparatus for generating a multiphasic defibrillation/cardioversion waveform as well as a multiphasic fibrillation inducing pulse train. The multiphasic fibrillation inducing waveform being applied to the same electrodes as the defibrillation/cardioversion waveform.

EP 0 589 252 A2

## BACKGROUND OF THE INVENTION

The present invention relates to implanted arrhythmia control devices, and more particularly to a non-invasive method and apparatus for inducing arrhythmias after the device is implanted. More specifically, it relates to a non-invasive method and apparatus for generating fibrillation inducing pulse trains for the purpose of testing an implanted cardioverter/defibrillator.

Ventricular fibrillation typically must be induced when an automatic implantable cardioverter defibrillator is implanted and for follow-up studies to test the effectiveness of the automatic implantable cardioverter defibrillator in defibrillating.

When implantable arrhythmia control devices are used, it is desirable to allow stimulation of the heart to induce arrhythmias after the device is implanted, without the need to introduce a separate stimulating lead/wire. That is, a non-invasive method of inducing arrhythmias is desirable.

In order to induce fibrillation for the purpose of testing an implanted arrhythmia control device, burst or ramped burst pacing at very fast stimulation rates has been used to induce ventricular fibrillation in some patients. However, due to the small energy levels involved and the relatively small size and placement of the pacing electrode system, this method does not successfully induce ventricular fibrillation. Programmed electrical stimulation or non-invasive premature stimulation has also been used to induce ventricular tachycardia, but does not always reliably induce ventricular fibrillation. Programmed electrical stimulation or non-invasive premature stimulation commonly consist of delivering a series of fixed rate pace pulses, followed by 1 to 5 pacing "extra-stimuli" at various shorter intervals coupled to the last fixed rate pulse. Both programmed electrical stimulation/non-invasive premature stimulation and burst pacing use the much smaller pacing electrodes which tend to localize the stimulation. Fibrillation is more easily induced when large portions of the heart are stimulated simultaneously.

While these prior systems generally are effective, there is room for improvement.

## SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a method and apparatus for generating a multiphasic fibrillation inducing pulse train via the defibrillation/ cardioversion leads and electrodes of an already implanted defibrillator to thereby test the implanted defibrillator non invasively.

Briefly, the present invention is directed to a method and apparatus for use with an implanted defibrillator, having an external programmer including telemetry means. The telemetry means is used to

communicate with an implantable device incorporating a multiphasic circuitry for non-invasively delivering a fibrillation inducing pulse train via the defibrillation/cardioversion leads and electrodes of the already implanted defibrillator. In this manner, the present invention facilitates testing of an already implanted defibrillator without the need to induce fibrillation by invasive techniques.

The above and other objects and advantages will become more readily apparent when reference is made to the following description taken in conjunction with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic diagram of the circuitry of an implanted defibrillator, capable of generating a multiphasic defibrillation waveform, and adapted to be used with an external programmer, including telemetry means, in accordance with the present invention to deliver a fibrillation inducing pulse train via the defibrillation/cardioversion leads and electrodes of the implanted defibrillator.

Figure 2 is a flow chart illustrating the operation of the circuitry shown in Figure 1.

Figure 3 is a graphical representation of a multiphasic fibrillation inducing pulse train generated by firmware in the circuitry of FIG. 1, which is used to induce fibrillation in a heart for the purpose of testing an implanted cardiac defibrillator.

Figure 4 is a graphical representation of an approximation of the fibrillation inducing pulse train shown in Figure 3, which can be generated by utilizing the ratiometric capabilities of the circuitry of Figure 1.

## DETAILED DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates an implantable electrical circuitry for generating a multiphasic defibrillation waveform. An external programmer, including telemetry means, is used to communicate with the implanted circuitry to deliver fibrillation inducing pulse trains via the defibrillation/cardioversion leads and electrodes of the already implanted defibrillator in accordance with the present invention.

Techniques for defibrillation/cardioversion have evolved over the years from a truncated exponentially decaying waveform of a capacitor to more sophisticated waveforms, such as multiphasic waveforms. In this regard, it has been found that multiphasic waveforms often are more effective in defibrillating the heart. The circuit for generating multiphasic defibrillation waveforms shown in FIG. 1, and the operation of which is illustrated by the flow chart in FIG. 2 is more fully disclosed in copending U.S. Patent Application S.N. , entitled: Method and Apparatus for Generating Multiphasic Defibrillation Waveforms Based on Pulse Width Ratios, which



was filed on the same date as this application. The disclosure of which copending application is hereby incorporated by reference.

In accordance with the present invention, the circuit shown in FIG. 1 for example, can be used to remotely induce fibrillation for the purpose of testing the effectiveness of the implanted defibrillator prior to discharging the patient from the hospital.

Traditionally, testing of an implanted defibrillator has been accomplished by passing a catheter into the patient and inducing fibrillation via the catheter. Recently, however, remote control of an already implanted defibrillator has been accomplished by using an external programmer device or other similar device. An external programmer includes telemetry means that provides non-invasive control and interrogation of an implanted defibrillator. The external programmer may include a telemetry wand to communicate with the implanted device via RF signals.

According to the present invention, by using an external programmer or other similar device, fibrillation can be induced via the leads and electrodes of the already implanted defibrillator.

With reference to FIG. 1, an external programmer 150 (or other similar device) having a telemetry wand 152 is used to non-invasively cause the circuitry 100 of the present invention to deliver a multiphasic fibrillation inducing pulse train, rather than a multiphasic defibrillation waveform. An ideally effective fibrillation inducing pulse train 140 is illustrated in Figure 3. All of the pulses constituting the pulse train 140 have the same nominal voltage  $V_n$  which is typically on the order of 15 volts but may be as low as 9 volts, with successive pulses alternating in polarity between negative and positive polarity. The pulse width  $t_w$  for each pulse is preferably 1.1 milliseconds, while the delay time  $t_d$  between successive pulses can range from 30 to 50 milliseconds. A delay time of 30 milliseconds provides a high rate of pulses, while a 50 millisecond delay time provides a slower rate of pulses. The pulse widths are shorter than those which are used for defibrillation purposes. Likewise, the pulse width percentages  $P_2, P_3, \dots, P_n$  are all programmed to equal 100 percent such that all pulses subsequent to the first have the same pulse widths  $t_2, t_3, \dots, t_n$  as the first pulse.

The circuitry 100 is provided with logic which, upon detecting via the external programmer 150 or other similar device the command to induce fibrillation, directly causes a pulse train to be emitted with a predetermined pulse width equal to  $t_w$ , a nominal voltage equal to  $V_n$ , and delay time equal to  $t_d$ . The logic can accomplish this by causing the charge control logic 108 to charge the capacitor 128 to a predetermined voltage equal to or slightly higher than  $V_n$ . Next, the additional logic temporarily overrides the circuitry 100 of Figure 1 causing switches s1 and s4 to close for  $t_w$  milliseconds, then causing the switches to open for

the delay time  $t_d$  and thereafter closing switches s2 and s3 for  $t_w$  milliseconds, this process being repeated by the additional logic until a predetermined period of time equal to the desired duration of the pulse train (preferably 2 - 5 seconds) has elapsed. In this manner, the pulse train is provided without having to detect any voltages other than the starting voltage of the capacitor.

Alternatively, Figure 4 illustrates a close approximation 140' of the pulse train 140 of Figure 3, which can be generated by using ratiometric capabilities of the circuitry 100. This approximation 140' is primarily achieved by choosing values of  $V_0$  and  $V_1$  which, in addition to being slightly greater than  $V_n$ , are very close to one another such that a shorter pulse width  $t_1$  (comparable to  $t_w$ , and shorter than that which is used for defibrillation purposes) is achieved for the first pulse. Likewise, the pulse width percentages  $P_2, P_3, \dots, P_n$  are all programmed to equal 100 percent such that all pulses subsequent to the first have the same pulse widths  $t_2, t_3, \dots, t_n$  as the first pulse.

The approximated fibrillation inducing pulse train 140' can also be generated without the need for programming the pulse width percentages. Instead, the circuitry 100 can be provided with logic which upon sensing via the external programmer 150 or other similar device the need to induce fibrillation, causes the contents of the data buffer 112 to be provided to the pulse control logic 118 in place of the result from the multiplier 110. Consequently, rather than providing the result from the multiplier 110 to the pulse control logic 118, the actual value of  $t_1$  from the data buffer 118 is provided. Hence, all subsequent pulses are automatically delivered with the same pulse width as  $t_1$ .

Furthermore, modifications may be made to the circuitry 100 shown in Figure 3, for the purpose of delivering fibrillation inducing pulse trains, without departing from the scope and spirit of the present invention. For instance, the pulses or "mini-shocks" can be delivered in alternating polarity as set forth above, or all in the same polarity. Each pulse is delivered as a monophasic fixed pulse width shock, with short charge cycles between pulses. The shocks are delivered to the defibrillation electrodes by the four switch  $S_1, S_2, S_3, S_4$  switch bridge network. Such use of the same output circuit for the fibrillation inducing pulses as the normal defibrillation pulse delivery has not previously been provided. The very high rate delivery through the larger shocking electrodes allow stimulation of a larger part of the heart.

Further, retriggering capability is provided to allow the delivery of a burst of pulses for any desired duration. The delivery being controlled by a user pressing and holding a button or key on the programmer. In a preferred embodiment the pulse train is 2 - 5 seconds long.

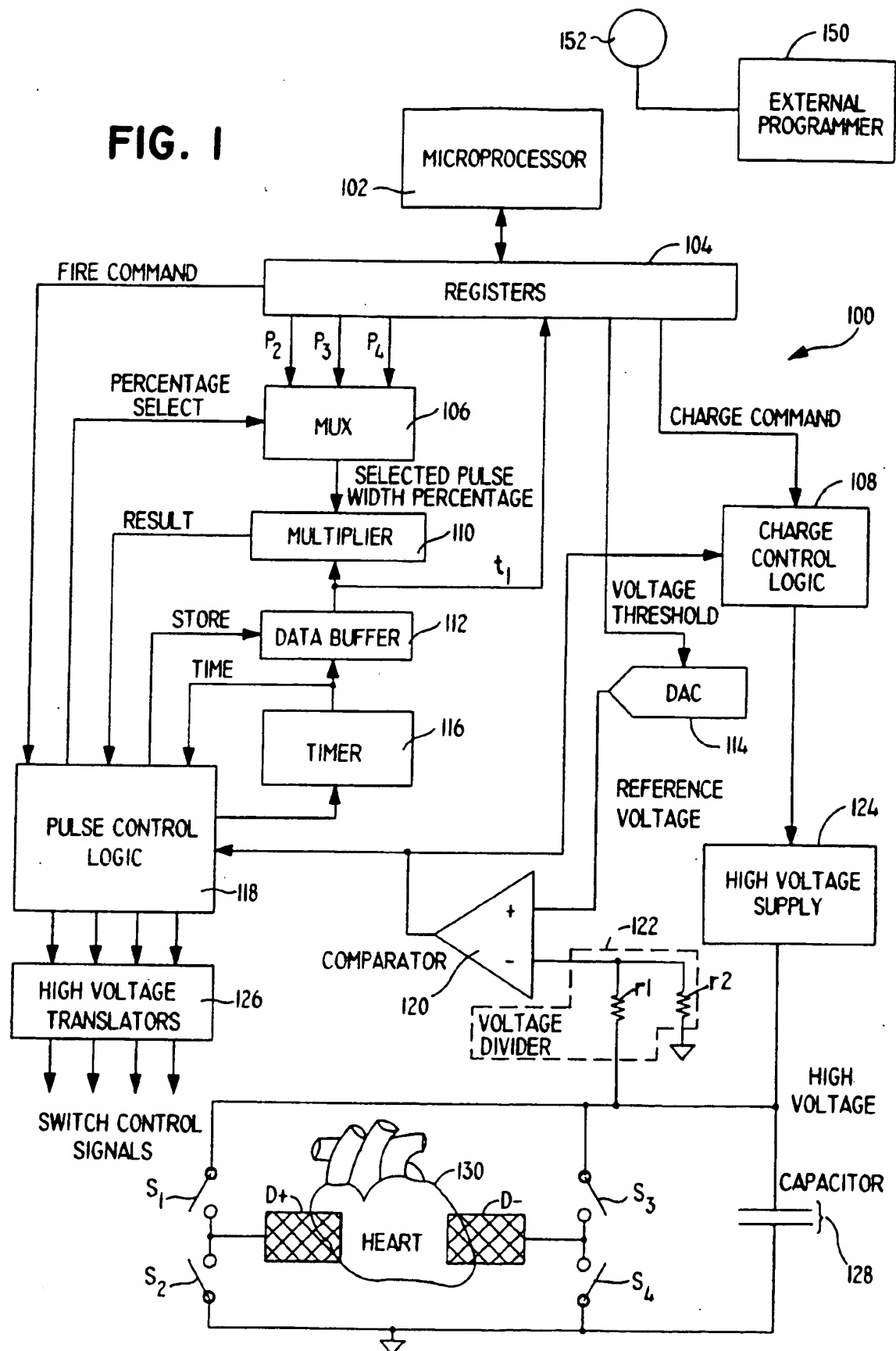
Alternative embodiments of the invention would provide higher rates of delivery of the fibrillation pulses, for instance at 8 to 16 milliseconds. Lower pulse amplitudes would result in less energy delivery, and higher output impedance with provide for better current limiting.

The above description is intended by way of example only and is not intended to limit the present invention in any way except as set forth in the following claims.

#### Claims

1. An implantable apparatus for generating a defibrillation/cardioversion waveform for application to defibrillation electrodes, including an external programming means for causing said implantable apparatus to generate a multiphasic fibrillation inducing pulse train, each of said pulses being separated by a delay time  $t_d$  with each pulse having a pulse width  $t_w$  and a nominal voltage  $V_n$ .
2. The apparatus of claim 1, wherein said delay time  $t_d$  is set between 30 - 50 milliseconds, said pulse width  $t_w$  is 1.1 milliseconds, and said nominal voltage  $V_n$  is 15 volts for each of the pulses, said pulse train being 2 - 5 seconds long.
3. The apparatus of claim 1, wherein said fibrillation inducing pulse train is delivered to said defibrillation electrodes.
4. The apparatus of claim 1, wherein said implantable apparatus includes logic means which in response to said external programming means causes said implantable apparatus to generate a fibrillation inducing pulse train with a predetermined pulse width and a predetermined time delay.

FIG. 1



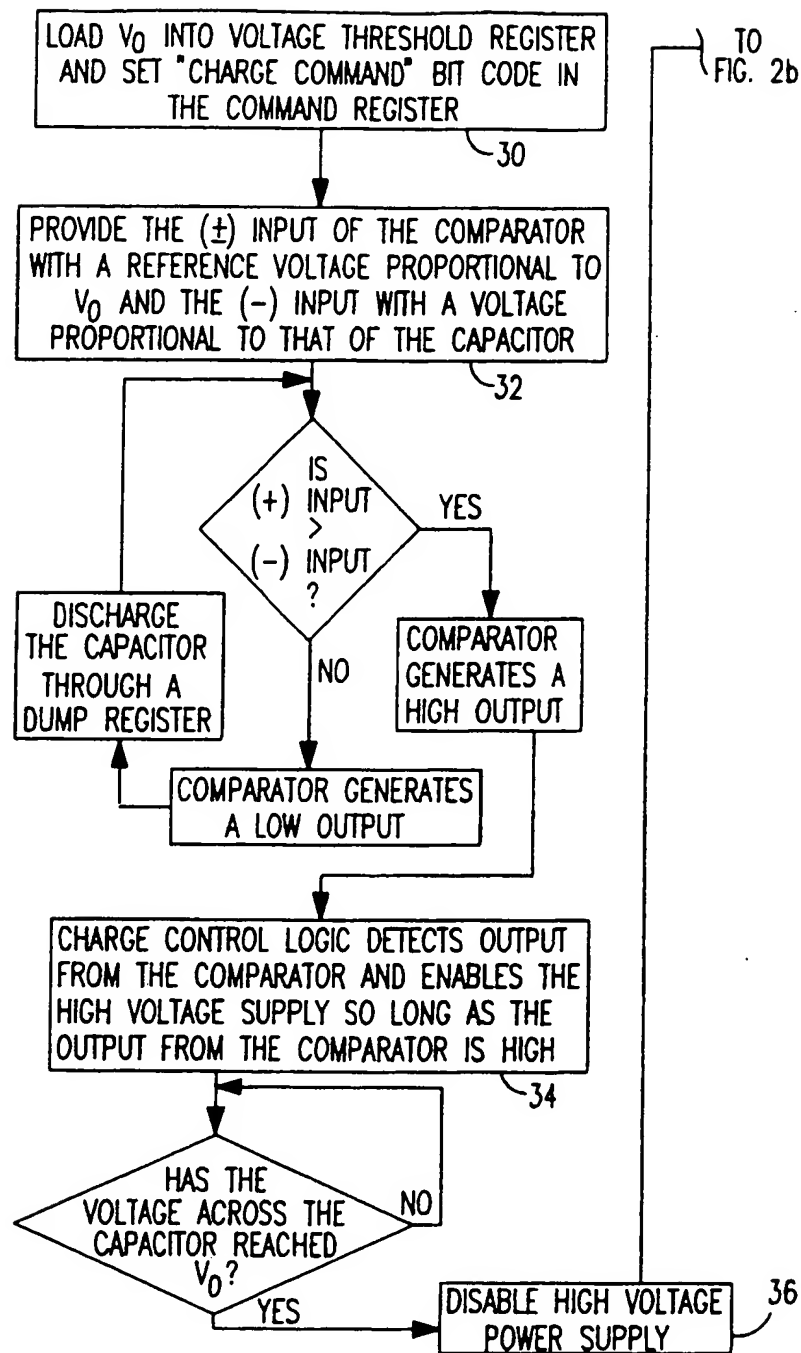


FIG. 2a

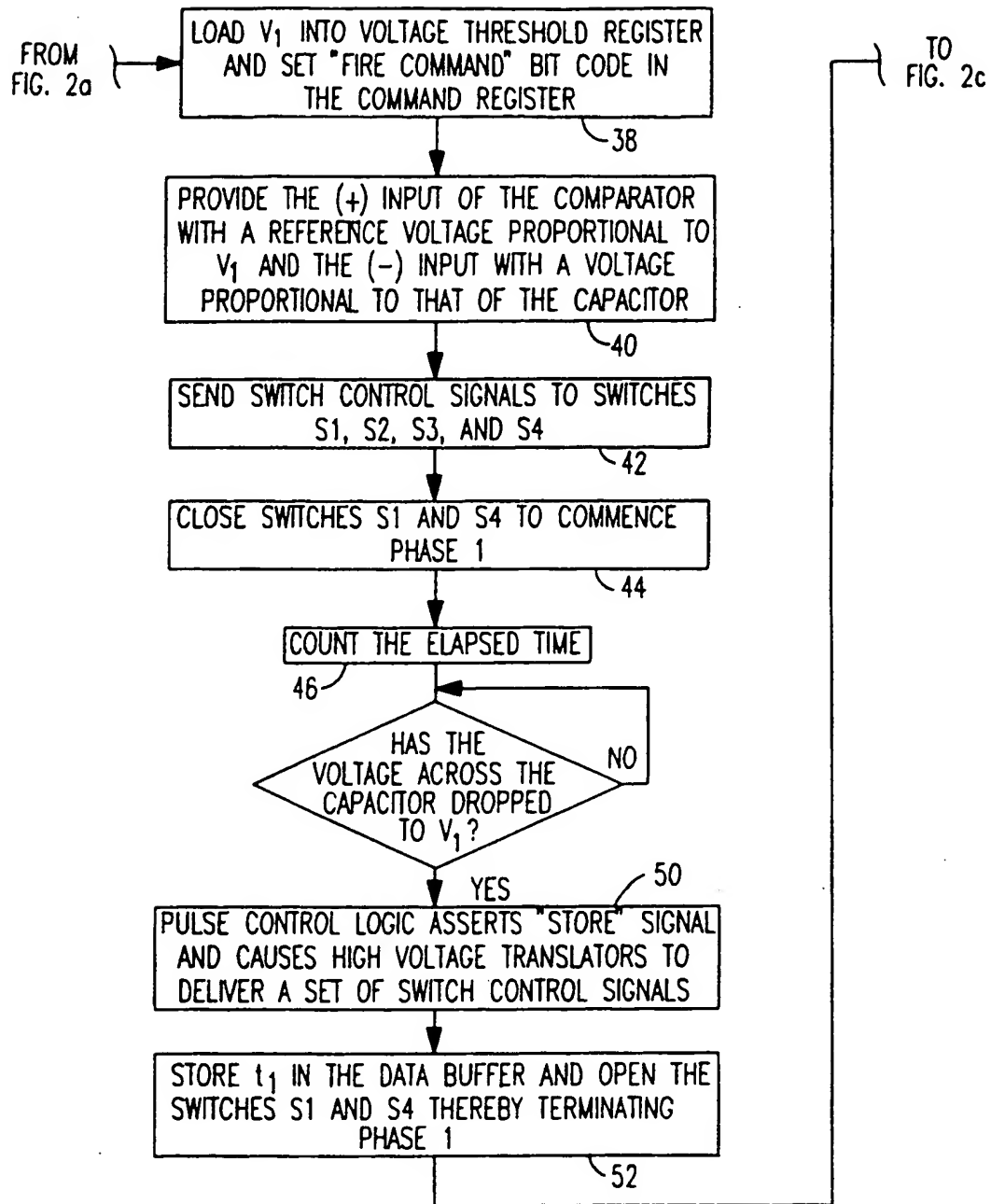


FIG. 2b

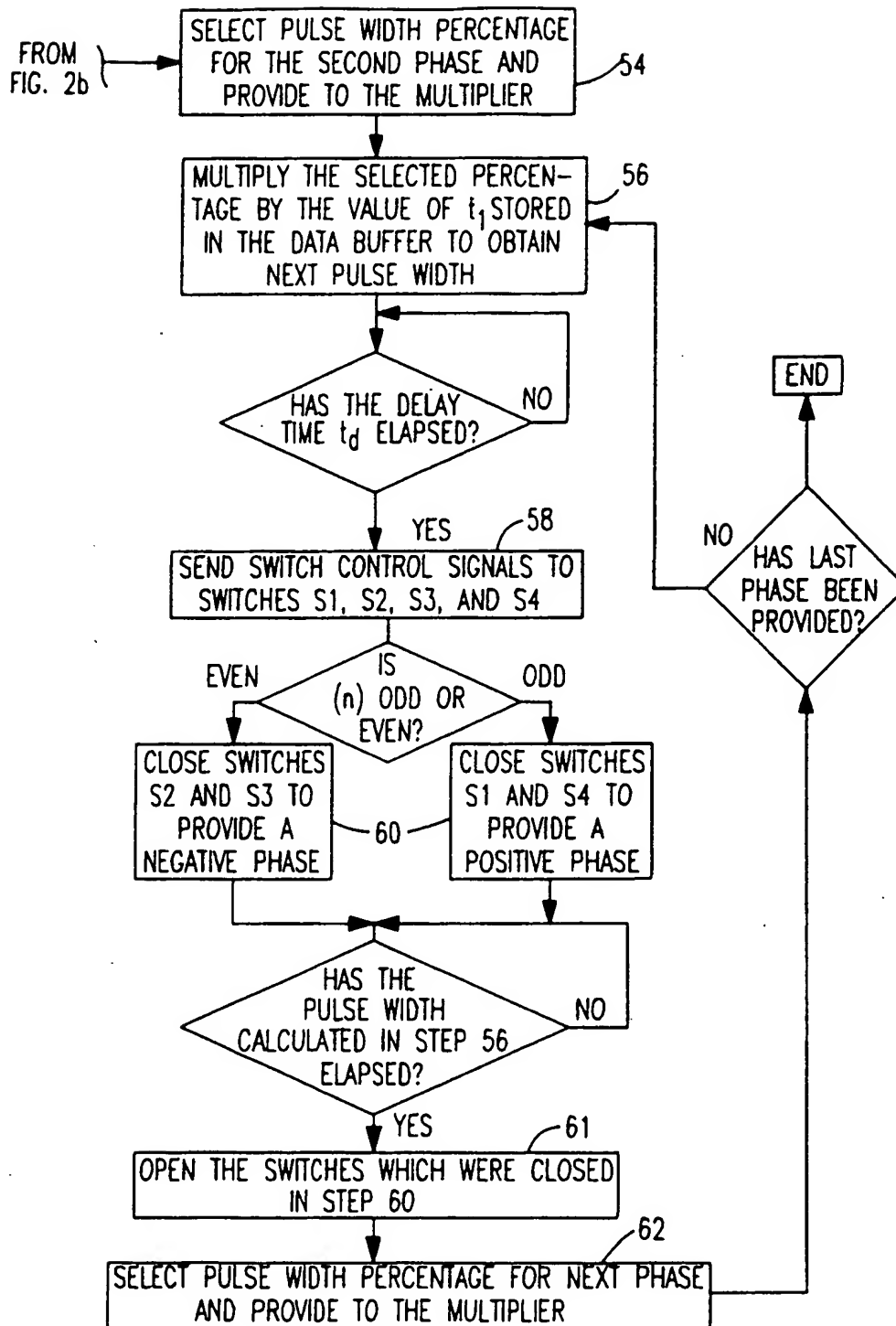


FIG. 2c

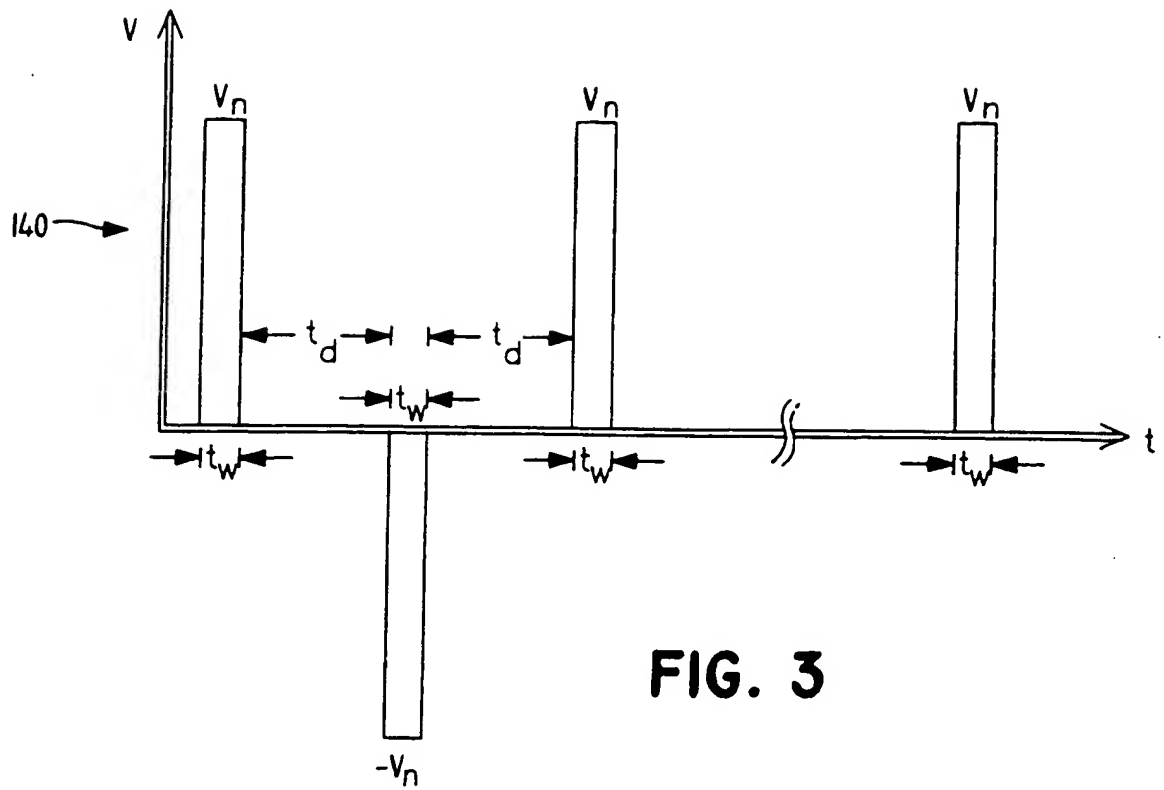


FIG. 3

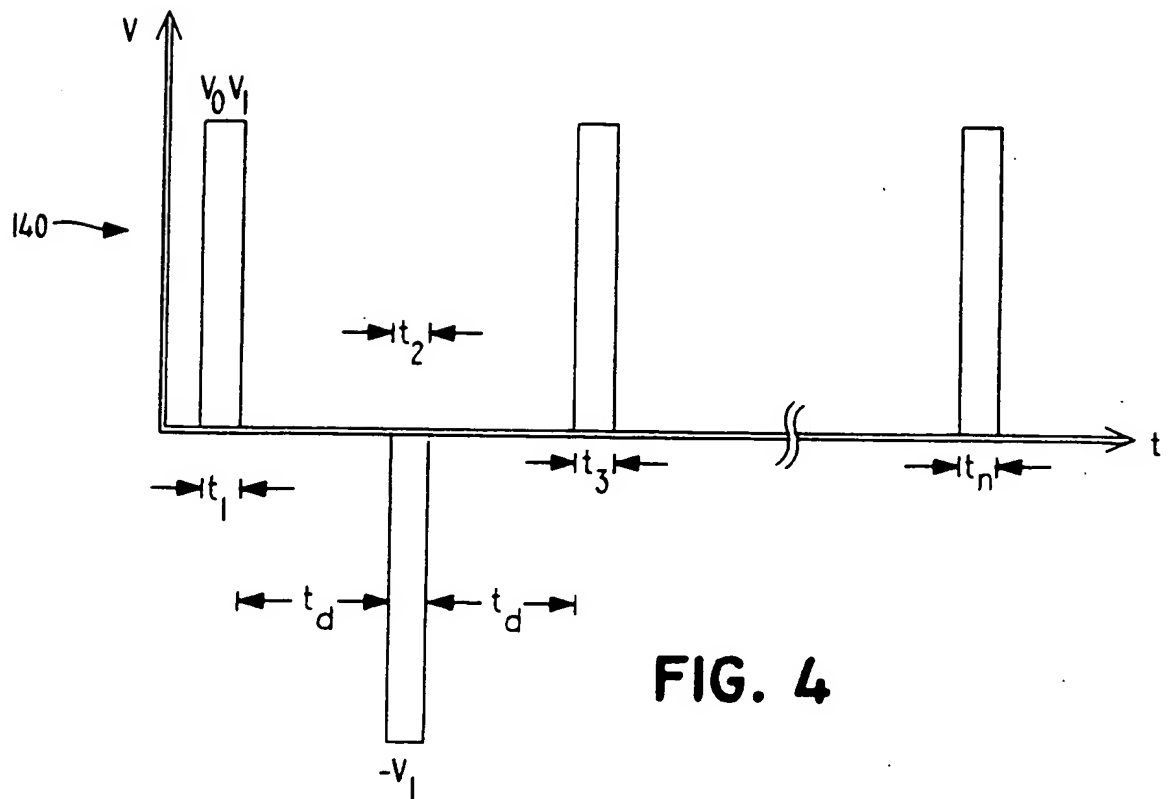


FIG. 4